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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/757,706

01/14/2004

Michael Ernest

LIFE-F-P01A

4469

23653 7590 05/19/2006

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EXAMINER

MELLER, MICHAEL V

ART UNIT

PAPER NUMBER

1655

DATE MAILED: 05/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/757,706	Applicant(s) ERNEST, MICHAEL	
	Examiner Michael V. Meller	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

This application contains claims directed to the following patentably distinct species of the claimed invention: the many different types of components in the protein mixture and enzyme pH adjustor formulation as claimed.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 14, are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record

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showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Frank Morkunas on 10/12/2005 a provisional election was made with traverse to elect the invention of betaine HCl and pepsin as the two components in the enzyme pH adjustor formulation and whey protein isolate and soy protein isolate as the two components in the protein mixture. Affirmation of this election must be made by applicant in replying to this Office action. The other components in the protein mixture and the enzyme pH adjustor formulation are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

It is noted that applicant elected glycine and bromolein as additional components of the enzyme pH adjustor formulation and maltodextrin and steviolide as additional components of the protein mixture.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over KR 2003025587 (abstract), Terry et al. (abstract, col. 1, lines 5-15, 50-end, col. 2, lines 1-10, the claims), KR 2002041162 (abstract) or JP 01132533 (abstract) taken with Craig et al. (col. 1, lines 1-10, col. 2, lines 1-50, col. 3, line 60-col. 4, line 15, col. 5, lines 15-30, the claims), Kamarei '650 (col. 5, line 50-col. 6, line 25) or Kamarei '425 (col. 5, line 40-col. 6, line 15), CN 1104062 (abstract), JP 403232480 (abstract), JP 03290166 (abstract) and JP 02000169502 (abstract).

KR 2003025587, Terry et al., KR 2002041162 and JP 01132533 all teach that pepsin and betaine HCl are known to be used in compositions to help improve digestion.

Craig et al. (col. 1, lines 1-10, col. 2, lines 1-50, col. 3, line 60-col. 4, line 15, col. 5, lines 15-30, the claims), Kamarei '650 (col. 5, line 50-col. 6, line 25) and Kamarei '425 (col. 5, line 40-col. 6, line 15) all teach that whey protein and soy protein are both also known to be used in compositions to help improve digestion.

CN '062 teaches that vitamin c is known to be used to aid in digestion.

JP '480 teaches that papaya is known to be used for promoting digestion.

JP '502 teaches that maltodextrin is known to be used to aid in digestion.

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Jp '166 teaches that lecithin is known to be used to aid in digestion.

It is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Sussman*, 1943 C.D. 518; *In re Pinten*, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

The reason or motivation to modify a reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. While there must be motivation to make the claimed invention, there is no requirement that the prior art provide the same reason as the applicant to make the claimed invention.

MPEP 2144 Sources of Rationale Supporting a Rejection Under 35 U.S.C. 103.
<http://www.uspto.gov/web/offices/pac/mpep/documents/2100_2144.htm>

Since the ingredients were all known to be used individually in the art for the same purpose, namely to improve/aid digestion, then it would have been obvious to use them together in the same composition.

To use the specific amounts of the ingredients is simply the choice of the artisan in an effort to optimize the desired results and can be arrived at by routine experimentation.

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The addition of a carrier which is a liquid substance which reads on water and a stabilizer which also could be water is obvious since water is included in the disclosed compositions in the various references as are many other carriers and stabilizers.

The soy protein and the whey protein were isolated from the native soybean and whey thus they are isolates.

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over KR 2003025587 (abstract), Terry et al. (abstract, col. 1, lines 5-15, 50-end, col. 2, lines 1-10, the claims), KR 2002041162 (abstract) or JP 01132533 (abstract) taken with JP 403232480 (abstract) and CN 1104062 (abstract).

KR 2003025587, Terry et al., KR 2002041162 and JP 01132533 all teach that pepsin and betaine HCl are known to be used in compositions to help improve digestion.

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The reason or motivation to modify a reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. While there must be motivation to make the claimed invention, there is no requirement that the prior art provide the same reason as the applicant to make the claimed invention.

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Since the ingredients were all known to be used individually in the art for the same purpose, namely to improve/aid digestion, then it would have been obvious to use them together in the same composition.

To use the specific amounts of the ingredients is simply the choice of the artisan in an effort to optimize the desired results and can be arrived at by routine experimentation.

The addition of a carrier which is a liquid substance which reads on water and a stabilizer which also could be water is obvious since water is included in the disclosed compositions in the various references as are many other carriers and stabilizers.

The soy protein and the whey protein were isolated from the native soybean and whey thus they are isolates.

The references show protein mixtures which are in the form of enzyme mixtures, see above citations.

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Claims 14-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Craig et al. (col. 1, lines 1-10, col. 2, lines 1-50, col. 3, line 60-col. 4, line 15, col. 5, lines 15-30, the claims), Kamarei '650 (col. 5, line 50-col. 6, line 25) or Kamarei '425 (col. 5, line 40-col. 6, line 15) taken with JP 03290166 (abstract) and JP 02000169502 (abstract).

Craig et al. (col. 1, lines 1-10, col. 2, lines 1-50, col. 3, line 60-col. 4, line 15, col. 5, lines 15-30, the claims), Kamarei '650 (col. 5, line 50-col. 6, line 25) and Kamarei '425 (col. 5, line 40-col. 6, line 15) all teach that whey protein and soy protein are both also known to be used in compositions to help improve digestion.

JP '502 teaches that maltodextrin is known to be used to aid in digestion.

Jp '166 teaches that lecithin is known to be used to aid in digestion.

It is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Sussman*, 1943 C.D. 518; *In re Pinten*, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

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make the claimed invention, there is no requirement that the prior art provide the same reason as the applicant to make the claimed invention.

MPEP 2144 Sources of Rationale Supporting a Rejection Under 35 U.S.C. 103.
<http://www.uspto.gov/web/offices/pac/mpep/documents/2100_2144.htm>

Since the ingredients were all known to be used individually in the art for the same purpose, namely to improve/aid digestion, then it would have been obvious to use them together in the same composition.

To use the specific amounts of the ingredients is simply the choice of the artisan in an effort to optimize the desired results and can be arrived at by routine experimentation.

The addition of a carrier which is a liquid substance which reads on water and a stabilizer which also could be water is obvious since water is included in the disclosed compositions in the various references as are many other carriers and stabilizers.

The soy protein and the whey protein were isolated from the native soybean and whey thus they are isolates.

The references show enzyme pH adjustor formulations which are in the form of acids, fats, carbohydrates, minerals, vitamins, antioxidants, etc, see above citations.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 571-272-0967. The examiner can normally be reached on Monday thru Thursday: 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'M. Meller', with a long horizontal flourish extending to the right.

Michael V. Meller
Primary Examiner
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MVM